

GERARDO V. NORIEGA et al.  
Application No. 09/644,201  
Page 2

PATENT

Amendments to the Claims:

Claims 10 and 12 are currently amended. This listing of claims will replace all prior versions, and listings of claims in the application:

Listing of Claims:

1. (Previously presented) An assembly for crossing occlusive or stenotic material, the assembly comprising:
  - a flexible, hollow guidewire comprising an axial passage, an outer diameter between approximately 0.009 inches and 0.035 inches, and a torquability and pushability to be advanced through a vascular body lumen without the need of a separate guidewire;
  - a housing removably coupled to a proximal end of the flexible, hollow guidewire;
  - and
  - a drive shaft rotatably and translatably extending through the axial passage of the guidewire;wherein the drive shaft comprises a distal tip that can be rotated and advanced to create a path that is larger than the outer diameter of the guidewire through the occlusive or stenotic material.
- 2.-3. (Canceled)
4. (Previously presented) The assembly of claim 1 further comprising a detachable motor coupled to a proximal end of the drive shaft that can impart a rotational movement to the distal tip of the drive shaft.
5. (Original) The assembly of claim 1 wherein a proximal end of the drive shaft can be manually rotated.
6. (Original) The assembly of claim 1 wherein the distal tip is flattened and twisted.

GERARDO V. NORIEGA et al.  
Application No. 09/644,201  
Page 3

PATENT

7. (Original) The assembly of claim 1 wherein the distal tip has a width that is larger than the width of the drive shaft.
8. (Original) The assembly of claim 1 wherein a distal end of the hollow guidewire is steerable.
9. (Canceled).
10. (Currently amended) The assembly of claim 9 1 wherein the housing comprises an actuator, wherein the drive shaft defines a longitudinal axis, and wherein movement of the actuator moves the drive shaft along the longitudinal axis.
11. (Previously presented) The assembly of claim 10 wherein the actuator advances the drive shaft up to 5 centimeters beyond a distal end of the hollow guidewire.
12. (Currently amended) The assembly of claim 9 1 wherein the housing comprises an infusion or aspiration port in communication with the axial passage of the hollow guidewire.
13. (Original) The assembly of claim 1 wherein the hollow guidewire is maintained in a substantially stationary position while the drive shaft is rotated and advanced.
14. (Original) The assembly of claim 1 wherein the distal tip of the drive shaft is radio-opaque.
15. (Original) The assembly of claim 1 wherein the drive shaft has riflings which facilitate proximal transportation of a removed occlusive or stenotic material.
16. (Original) The assembly of claim 1 further comprising a support system having a distal end, wherein the hollow guidewire passes through the support system such that the distal tip is positioned beyond the distal end of the hollow guidewire and support system.

GERARDO V. NORIEGA et al.  
Application No. 09/644,201  
Page 4

PATENT

17. (Original) The assembly of claim 16 wherein the support system comprises placing means disposed near the distal end for centering or directing the distal end of the support system within the body lumen.

18. (Previously presented) The assembly of claim 16 wherein the hollow guidewire is advanceable through the vascular body lumen without the use of the support system.

19. (Original) The assembly of claim 1 wherein the drive shaft defines a longitudinal axis, wherein the distal tip is deflected off the longitudinal axis.

20. (Previously presented) A guidewire system for passing through an occlusion or stenosis, the system comprising:

a flexible, hollow guidewire having a steerable distal end, a proximal end, and a lumen therebetween, wherein the hollow guidewire has an outer diameter between approximately 0.009 inches and 0.035 inches and a torqueability and pushability to be advanced through a body lumen without the need of a separate guidewire;

a drive shaft movably disposed within the hollow guidewire, the drive shaft having a longitudinal axis, a proximal end, and a distal tip portion;

a rotating mechanism removably coupled to the proximal end of the drive shaft;  
and

an actuator coupled to the drive shaft for controlling the axial movement of the drive shaft;

wherein the activation of the actuator advances the rotatable drive shaft from a retracted position to an extended position, wherein the rotating distal tip portion in an extended position can create a path through the occlusion or stenosis.

21. (Original) The system of claim 20 wherein the distal tip portion is flattened and twisted.

GERARDO V. NORIEGA et al.  
Application No. 09/644,201  
Page 5

PATENT

22. (Previously presented) The system of claim 20 wherein the distal tip portion creates a path forward of the hollow guidewire that is at least as large as the outer diameter of the hollow guidewire.

23. (Previously presented) The system of claim 20 wherein the distal tip portion creates a path forward of the hollow guidewire that is no larger than the outer diameter of the hollow guidewire.

24. (Original) The system of claim 20 wherein the distal tip portion comprises a plurality of wires connected at their ends, a plurality of wires unconnected at their ends, spiral with a blunt tip, or a loop.

25. (Canceled)

26. (Canceled)

27. (Original) The system of claim 20 wherein the rotating mechanism and actuator are coupled together such that the drive shaft is rotated and advanced simultaneously.

28. (Original) The system of claim 20 wherein the rotating mechanism and actuator are independently rotated and advanced.

29. (Original) The system of claim 20 wherein the rotating mechanism is removably attached to the drive shaft.

30. (Original) The system of claim 20 wherein the lumen of the hollow guidewire is configured to aspirate fluids and debris from or infuse fluids into the occlusion or stenosis.

31. (Previously presented) A system for crossing an occlusion or stenosis within a body lumen, the system comprising:

GERARDO V. NORIEGA et al.  
Application No. 09/644,201  
Page 6

PATENT

a flexible, hollow guidewire having a proximal end, a distal end, and an axial passage extending to a distal tip at the distal end, wherein the guidewire has an outer diameter between approximately 0.009 inches and 0.035 inches and a torquability and pushability to be advanced through a vascular body lumen;

a drive shaft rotatably and translatably receivable in the axial passage of the guidewire;

a housing removably coupled to the proximal end of the flexible, hollow guidewire; and

a flattened and twisted distal tip attached to the drive shaft that can create a path in front of the distal end of the guidewire, wherein the drive shaft and distal tip are moveable between an axially retracted configuration and an axially extended configuration.

32. (Original) The system of claim 31 wherein the distal tip in the axially retracted configuration has a profile no larger than that of the distal tip

33. (Original) The system of claim 31 wherein the distal tip is sharpened.

34. (Original) The system of claim 31 wherein the distal tip comprises at least two turns.

35. (Canceled).

36. (Previously presented) The system of claim 31 wherein the hollow guidewire has a steerable distal end.

37. (Canceled)

38. (Original) The system of claim 31 further comprising a rotating mechanism coupled to a proximal end of the drive shaft to facilitate rotation of the drive shaft.

39. (Previously presented) The system of claim 38 wherein the rotating mechanism is detachable from a proximal end of the drive shaft.

GERARDO V. NORIEGA et al.  
Application No. 09/644,201  
Page 7

PATENT

40.-66. (Canceled)

67. (Previously presented) A kit comprising:

a flexible, hollow guidewire having an axial passage, an outer diameter between approximately 0.009 inches and 0.035 inches, and a torqueability and pushability to be advanced through a body lumen without the need of a separate guidewire;

a rotatable drive shaft having a shaped distal tip, the rotatable drive shaft being removably received within the passage of the hollow guidewire;

a housing that is removably coupleable to a proximal end of the hollow guidewire;

instructions for use in passing through occlusions in a body lumen comprising rotating the drive shaft within the steerable hollow guidewire and advancing the drive shaft into the occlusive material to create a path through the occlusive material; and

a package adapted to contain the hollow guidewire, rotatable drive shaft, and the instructions for use.

68. (Original) The kit of claim 67 wherein rotation of the shaped distal tip creates a profile that is at least as large as the outer diameter of the hollow guidewire.

69. (Original) The kit of claim 67 wherein rotation of the shaped distal tip creates a profile that is no larger than the outer diameter of the hollow guidewire.

70. (Canceled).

71. (Canceled).

72. (Original) The kit of claim 67 wherein the hollow guidewire has a steerable distal portion.

GERARDO V. NORIEGA et al.  
Application No. 09/644,201  
Page 8

PATENT

73. (Original) The kit of claim 67 further comprising a support or access system, wherein the support or access system is sized to removably receive the hollow guidewire and position a distal end of the hollow guidewire adjacent the occlusion.

74. (Original) The kit of claim 73 wherein the support or access system comprises an atherectomy catheter, support catheter, a balloon angioplasty catheter, a stenting catheter, infusion catheter, rotational catheter, extraction catheter, or a guiding catheter.

75. (Original) The kit of claim 74 further comprising a second guidewire, wherein the support or access system is advanced through the body lumen over the second guidewire.

76. (Original) The kit of claim 67 further comprising a power supply and a motor, wherein the motor can be coupled to a proximal end of the rotatable drive shaft so as to rotate the drive shaft.

77. (Original) The kit of claim 76 further comprising attachment mechanism for detachably coupling the motor to the drive shaft.

78. (Original) The kit of claim 76 wherein the power supply comprises a plastic sheath cover.

79. (Previously presented) The kit of claim 77 wherein the motor is movably housed within a housing, wherein the housing is removably coupled to the hollow guidewire through a luer.

80. (Previously presented) An assembly for crossing occlusive or stenotic material, the assembly comprising:

a flexible guidewire comprising an axial passage, an outer diameter between approximately 0.009 inches and 0.035 inches, and a torqueability and pushability to be advanced through a body lumen without the need of a separate guidewire;

GERARDO V. NORIEGA et al.  
Application No. 09/644,201  
Page 9

PATENT

a housing removably coupled to a proximal end of the flexible guidewire; and  
a drive shaft movably extending through the axial passage of the guidewire;  
wherein the drive shaft comprises a distal tip that extends beyond the guidewire to  
create a path through the occlusive or stenotic material.

81. (Previously presented) An assembly for crossing occlusive or stenotic  
material, the assembly comprising:

a guidewire comprising an axial passage, an outer diameter between  
approximately 0.009 inches and 0.035 inches, and a torqueability and pushability to be advanced  
through a body lumen without the need of a separate guidewire;

a housing removably coupled to a proximal end of the flexible guidewire; and  
a drive shaft movably extending through the axial passage of the guidewire;  
wherein the drive shaft comprises a distal tip that extends distally beyond the  
guidewire,

wherein the drive shaft may be oscillated or rotated to create a path through the  
occlusive or stenotic material.